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contract that supplies any administrative or care-related service or materials to the PACE organization.

- (1) PACE organizations must develop policies and procedures for handling any direct or indirect conflict of interest by a member of the governing body or by the member's immediate family.
- (2) In the event of a direct or indirect conflict of interest by a member of the PACE organization's governing body or his or her immediate family member, the board member must—
- (i) Fully disclose the exact nature of the conflict to the board of directors and have the disclosure documented; and
- (ii) Recuse himself or herself from discussing, negotiating, or voting on any issue or contract that could result in an inappropriate conflict.
- (c) Disclosure and recusal requirements. A PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71335, Dec. 8, 2006]

§ 460.70 Contracted services.

- (a) General rule. The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services as described in § 460.100.
- (b) Contract requirements. A contract between a PACE organization and a contractor must meet the following requirements:
- (1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to the following:
- (i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements.
- (ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.

- (iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality assessment and performance improvement activities.
- (2) A contractor must be accessible to participants, located either within or near the PACE organization's service area.
- (3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization.
- (c) List of contractors. A current list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.
- (d) Content of contract. Each contract must be in writing and include the following information:
 - (1) Name of contractor.
- (2) Services furnished (including work schedule if appropriate).
 - (3) Payment rate and method.
- (4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation, and termination.
- (5) Contractor agreement to do the following:
- (i) Furnish only those services authorized by the PACE interdisciplinary team.
- (ii) Accept payment from the PACE organization as payment in full, and not bill participants, CMS, the State administering agency, or private insurers.
- (iii) Hold harmless CMS, the State, and PACE participants if the PACE organization does not pay for services performed by the contractor in accordance with the contract.
- (iv) Not assign the contract or delegate duties under the contract unless it obtains prior written approval from the PACE organization.
- (v) Submit reports required by the PACE organization.
- (vi) Agree to perform all the duties related to its position as specified in this part.
- (vii) Participate in interdisciplinary team meeting as required.
- (viii) Agree to be accountable to the PACE organization.

- (ix) Cooperate with the competency evaluation program and direct participant care requirements specified in § 460.71.
- (e) Contracting with another entity to furnish PACE Center services. (1) A PACE organization may only contract for PACE Center services if it is fiscally sound as defined in §460.80(a) of this part and has demonstrated competence with the PACE model as evidenced by successful monitoring by CMS and the State administering agency.
- (2) The PACE organization retains responsibility for all participants and may only contract for the PACE Center services identified in §460.98(d).

 $[64\ {\rm FR}\ 66279,\ {\rm Nov.}\ 24,\ 1999,\ {\rm as}\ {\rm amended}\ {\rm at}\ 67\ {\rm FR}\ 61505,\ {\rm Oct.}\ 1,\ 2002;\ 71\ {\rm FR}\ 71335,\ {\rm Dec.}\ 8,\ 2006]$

§ 460.71 Oversight of direct participant care.

- (a) The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position.
- (1) The PACE organization must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff.
- (2) The PACE organization must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors).
- (3) The competency program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals.
- (4) The PACE organization must designate a staff member to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.
- (b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

- (1) Comply with any State or Federal requirements for direct patient care staff in their respective settings.
- (2) Comply with the requirements of §460.68(a) regarding persons with criminal convictions.
- (3) Have verified current certifications or licenses for their respective positions.
- (4) Are free of communicable diseases and are up to date with immunizations before performing direct patient care.
- (5) Have been oriented to the PACE program.
- (6) Agree to abide by the philosophy, practices, and protocols of the PACE organization.

[67 FR 61505, Oct. 1, 2002, as amended at 71 FR 71335, Dec. 8, 2006]

§ 460.72 Physical environment.

- (a) Space and equipment—(1) Safe design. A PACE center must meet the following requirements:
- (i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.
- (ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant.
- (2) Primary care clinic. The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining.
- (3) Equipment maintenance. (i) A PACE organization must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.
- (ii) A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the organization's written plan.
- (b) Fire safety—(1) General rule. Except as otherwise provided in this section—
- (i) A PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association